

**REMARKS/ARGUMENTS**

Claims 1-19 are presented for Examiner Redding's consideration.

Pursuant to 37 C.F.R. § 1.111, reconsideration of the present application in view of the foregoing amendments and the following remarks is respectfully requested.

In the Office Action mailed October 23, 2003, the Examiner indicated that an election to prosecute the invention of group 1 (as identified in the Office Action), claims 1-7, was made. Applicants' attorney affirms this election and accordingly withdraws claims 8-19.

Applicants acknowledge the Examiner's indication that claims 5-7 are allowable.

By way of the Office Action mailed October 23, 2003, the Examiner rejected claims 1-4 under 35 U.S.C. § 103 as allegedly being obvious to one of ordinary skill in the art at the time the invention was made and thus unpatentable over U.S. Patent Number 4,641,662 to Jaicks (hereinafter "Jaicks" or the "662 patent") in view of U.S. Patent Number 3,828,765 to McDonald (hereinafter "McDonald" or the "325 patent"). This rejection is respectfully **traversed** to the extent that it may apply to the presently presented claims.

In making the rejection the Examiner stated that "the Jaicks patent discloses an endocervical sampling tool which comprises a sampling end (20) which anticipates the claimed 'second end'." The Examiner also contends that McDonald also discloses an endocervical sampling tool with a urethral head which reads on the claimed first end of the present application. The Examiner contends that it would have been obvious to one skilled in the art to interchange the handle end of Jaicks with the urethral head in view of the disclosed endocervical sampling.

Applicants respectfully disagree with the Examiner's rejection and the reasons therefor. Applicant's respectfully submit that while Jaicks has an end, the teachings of Jaicks do not disclose or suggest that the device thereof incorporate a first end such as that described in the present application. More specifically, Jaicks teaches that it desirable for the end cited by the Examiner to be separable from the tool in order to insure all of the sample material is transferred to a specimen bottle so as to prevent a misdiagnosis.

As noted above, the Examiner also relies on McDonald in rejecting claims 1-4 of the present invention. Like the Jaicks reference, the teachings found in the McDonald reference do not provide support for the Examiner's rejections. For example, the test instrument of McDonald is intended for use in collecting samples from the patient and, more specifically, mucous and other genitourinary

secretions from the glands and ducts of a patient. Because the test instrument of McDonald is intended to actually take the secretions from the patient, the handle of the instrument must be of sufficient length to allow the head of the device to extend into the urethra of a patient. Further, the teachings of McDonald indicate that it is essential or critical that the secretions be scraped or "milked" from the patient in such a way that all of the secretions are retained by the head of the test instrument and that a sufficient quantity of secretions be collected as the failure to extract such secretions will usually result in the failure to diagnose the disease (i.e. gonorrhea) and avoid further dissemination thereof. Still further, the instrument of McDonald needs to be able not only to express mucous secretions, pus, fluid, or other material from the various glands and ducts of the uterus and urethra, but also must be able to gather all of the secretions and the like, and then be able to transfer all of the secretions and the like for testing. The inability to be able to collect all of these secretions and the like is unacceptable according to the teachings of McDonald as the potential for a missed diagnosis is high in such cases. Thus, McDonald requires that the head of the device not only be able to express secretions and the like but also that all of the secretions must be collected. Any thing less than a complete collection of the secretions goes against the teachings of McDonald. Further still, in order to achieve a complete transfer of the secretions and the like, the head of the McDonald device needs to be removable from the handle so that all of the secretions and the like on the head of the device are transferred to a specimen bottle to insure an accurate diagnosis. Additionally, the head of the test instrument of McDonald requires a spaced end wall from the concave side of the head. The spaced end wall being designed to define a recess which will retain mucous secretions and the like.

The device of the present application varies from the teachings and necessities of McDonald in a variety of ways. For example, the specimen-handling tool of the present invention need not be of the length required by McDonald (i.e. able to extend into the uterus or urethra of a patient from outside the patient). Further, the present invention is not intended to express secretions from a patient, nor do the ends thereof provide the minimum secretion and like retention capabilities required by McDonald. The specimens encountered by the tool of the present application will generally be a biopsy specimen which for example may have been obtained via biopsy forceps or the like. Once the biopsy specimen has been removed from the body of a patient, the tool of the present invention may then be used to transfer the specimen to a diagnostic test kit. The tool may be used to spear the specimen to allow transfer to the test kit or one end of the tool may be used to lift the specimen to allow transfer to a test kit. The size, shape, and contours of the tool of the present application would not retain the secretions and the like which McDonald and Jaicks teach are

essential. As such McDonald and Jaicks teach away from use of the tool of the present application.

Furthermore, the tool of the present application does not require such a wall means extending laterally from the concave side of a crescent shaped head.

Again, as the Applicants have herein discussed the cited references in relation to claim 1, claims 2-4 are similarly distinguishable not only because of the patentability of the independent claims but also because of the combination of the subject matter of each of the dependent claims with their independent claim which makes each claim further distinguishable, and which is not taught or suggested by the cited references, singly or in combination. Accordingly, it is respectfully submitted that the Examiner's rejection of claims 2-4 should be withdrawn.

For the reasons stated above, it is respectfully submitted that all of the presently presented claims are in form for allowance.

Please charge any prosecutorial fees which are due to Kimberly-Clark Worldwide, Inc. deposit account number 11-0875.

The undersigned may be reached at: 770-587-7183.

Respectfully submitted,

PETERSON ET AL.

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#### CERTIFICATE OF MAILING

I, William W. Letson, hereby certify that on February 23, 2004 this document is being deposited with the United States Postal Service as first-class mail, postage prepaid, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: 

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